SEP 2 9 2004

15 September 2004

510K Summary

Model 8600 Vital Signs Monitor

Contact: Alex Kaplan
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Trade Name: 8600 Vital Signs Monitor

Common Name: Vital Signs Monitor

Classification Name: Monitor, Physiological, Patient (74 MWI)

Substantial Equivalence is claimed to : CSI Model 8100 / 8500 Vital Signs Monitor (K012059)

Device Description:
The 8600 monitor measures and displays real time physiological data of the patient, including waveforms and numerical data. The 8600 can be configured to monitor one or more of the following parameters: ECG, Noninvasive BP (NIBP), Invasive BP (IBP), SpO_2, Temperature, Respiration, CO_2, N_2O, O_2 and Halogenated Anesthetic Agents. For all these vital parameters, the 8600 will be capable of limit alarms and alerts, printing of strip chart recordings and storing trends for retrospective review.

Intended Use:
This system is intended to monitor physiological parameters of patients within any healthcare environment. The user, responsible to interpret the monitored data made available, will be a professional health care provider. Physiological data, system alarms and patient data analysis will be available to the care provider from the monitor.

Comparison with predicate device:
Criticare Systems Inc. has developed and distributed physiological monitoring devices worldwide since its inception in 1984. The 8600 monitor utilizes existing core technologies from the predicate monitor for patient monitoring of ECG, NIBP, IBP,

Resp, SpO_2, Temp, CO_2, N_2O, O_2 and Halogenated Anesthetic Agents. The 8600 monitor is MR Compatible per it's labeling claims. The patient data collected by the 8600 monitor is displayed for the user on a flat panel display as on the predicate device. The 8600 monitor utilizes Active TFT LCD color display technology. Membrane key panels and rotary push button navigation provides a user interface equivalent to the predicate device. The packaging design of the 8600 monitor is molded plastic and aluminum and allows for it to be either a stationary monitor or to be used during patient translocation within the healthcare facility, as did the predicate 8100 / 8500 monitor.

Determination of Substantial Equivalence:

The 8600 monitor performance for each monitoring modality has been confirmed to be equivalent to the predicate device. Additionally, the 8600 complies with applicable safety and performance standards (detailed below) for each monitoring modality and verification of compliance has been completed. The patient monitoring technologies present in the 8100 monitor have been in clinical use for at least six years in the predicate devices. CSI's field experience with these modalities in the predicate device has been satisfactory. This combination of equivalence testing, applicable objective standards compliance and field experience substantiates a high level of confidence in the safety and efficacy of the 8600 monitor.

Therefore, the 8600 monitor is substantially equivalent to the predicate device.

Compliance to standards and regulations:
The 8600 Vital Signs Monitor complies with the following national and international standards:

Safety
EN 60601-1 Medical Electrical Safety
IEC 601-1-2 EMC Compliance
ISO 10993-5,10-11 Biocompatibility

Performance
EN 60601-2-30 NIBP Safety
EN 1060-1 NIBP Performance
EN 1060-3 NIBP Performance {including EN 475 Alarm Performance}
AAMI SP-10 NIBP Performance
EN 60601-2-27 ECG Safety
AAMI EC-13 Basic ECG Performance
EN 865 Oximetry Performance (Equivalent to ASTM F 1415)
EN 864 Capnometry Performance (Equivalent to ASTM F 1456)
EN 60601-2-34 Invasive Blood Pressure Safety
EN ISO 11196 Anesthetic Gas Monitor Performance (Equivalent to ASTM F 1452)
EN 12598 Oxygen Analyzer Performance (Equivalent to ASTM F 1462)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2004

Criticare Systems, Inc.
c/o Mr. Alex Kaplan
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20925 Crossroads Circle
Suite 100
Waukesha, WI 53186-4054

Re: K042569
Trade Name: Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: September 18, 2004
Received: September 21, 2004

Dear Mr. Kaplan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042569

510(k) NUMBER (IF KNOWN) : _____

DEVICE NAME: Vital Signs Monitor

Indications for Use

This system is intended to monitor physiological parameters of patients within any healthcare environment. The user, responsible to interpret the monitored data made available, will be a professional health care provider. Physiological data, system alarms and patient data analysis will be available to the care provider from the monitor.

Prescription Use X (Per 21 CFR 801.109) OR Over – the - Counter – Use____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042569

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)